the cigarette rod than the regular-strength Lucky Strike, its nicotine yield on the FTC smoking machine (0.15 mg per cigarette) was *90% lower* than the yield of the Lucky Strike (1.46 mg per cigarette).

Barclay was able to combine the highest total nicotine content with the second-lowest measured nicotine yield by relying on a "channel-ventilated" filter system. An investigation commenced by FTC in 1981 found that air flow through these channels is compromised during actual smoking and that, as a result, Barclay actually delivered considerably more nicotine and tar to the smoker than is obtained using the FTC's testing method. In 1983, the FTC successfully sued to enjoin Brown & Williamson from using nicotine, tar, and carbon monoxide results obtained from the FTC's smoking machines in Barclay advertising. *See* 60 FR 41718.

While Barclay is a striking example of a filter that delivers more nicotine to its smokers than to a smoking machine, the use of ventilation systems that can be blocked by smokers is common. As FDA reported in the Jurisdictional Analysis, the evidence in the record indicates that 32% to 69% of smokers of low-tar cigarettes block ventilation holes. *See* 60 FR 41717.

In sum, the evidence in the record supports a finding that the increase in nicotine deliveries relative to tar deliveries produced by selective filtration and ventilation result from the deliberate design choices of the manufacturers. The manufacturers do not persuasively refute this finding. Accordingly, the Agency finds that the manufacturers use filtration and ventilation technologies that are designed to selectively remove more tar than nicotine.

c. The Manufacturers Use Chemical Additives to Increase the Delivery of "Free" Nicotine

The evidence in the record also supports a finding that the cigarette manufacturers control and manipulate nicotine deliveries through chemical manipulation. One way they do this is through the use of ammonia technologies that increase the delivery of "free" nicotine to smokers by raising the alkalinity or pH of tobacco smoke. "Free" nicotine is also sometimes referred to as "volatile," "extractable," or "non-ionized" nicotine. The use of ammonia compounds to increase pH is an outgrowth of the industry's product development research to improve the efficient use of smoke nicotine through pH modification. *See* section II.C.3., above.

The use of ammonia compounds is common in the cigarette industry. Ammonia compounds have been regularly identified in the list of cigarette ingredients submitted by the industry to the Department of Health and Human Services.[747] Indeed, the comments of the cigarette manufacturers concede that several ammonia-related compounds are used in the manufacture of cigarettes.[748]

An article in the *Wall Street Journal* describes the extent of the industry's reliance on ammonia technology.[749] According to the article, which is based on two major Brown & Williamson internal reports, Brown & Williamson adds ammonia compounds to "almost all" of its nonmenthol brands; Brown & Williamson views ammonia technology as "the

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[747] Joint Comment of Cigarette Manufacturers, Comment (Jan. 2, 1996), Vol. IV, at 84. *See* AR (Vol. 535 Ref. 96).

[748] *Id.*

[749] Freedman AM, Impact booster tobacco firm shows how ammonia spurs delivery of nicotine, *Wall Street Journal* (Oct. 18, 1995). *See* AR (Vol. 639 Ref. 2).

soul of Marlboro" and "the key factor" that "makes Marlboro a Marlboro"; and Brown & Williamson found that ammonia technology was also used by RJR, Lorillard, and American Tobacco Co.[750] In congressional testimony, Thomas Sandefur, the CEO of Brown & Williamson, confirmed the widespread use of ammonia within the cigarette industry.[751]

It is well established that the addition of ammonia compounds to tobacco increases pH. This increase transforms nicotine that is "bound" in nicotine salts to "free" nicotine.[752] This effect is described in Brown & Williamson's 1991 "Handbook for Leaf Blenders and Product Developers," which states that "*[a]mmonia, when added to a tobacco blend, reacts with the indigenous nicotine salts and liberates free nicotine.*"[753]

Changing the chemical form of nicotine from a bound nicotine salt to free nicotine has several significant consequences, according to the evidence in the administrative record. First, it increases the quantity of nicotine that is transferred from the cigarette to

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[750] *Id.*

[751] *Regulation of Tobacco Products (Part 3): Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives*, 103d Cong., 2d Sess. 224-225 (Jun. 23, 1994) (statement of Thomas Sandefur). *See* AR (Vol. 709 Ref. 3).

[752] *See, e.g.*, Armitage AK, Turner DM, Absorption of nicotine in cigarette and cigar smoke through the oral mucosa, *Nature*, Jun. 27, 1970;226:1231-1232. *See* AR (Vol. 45 Ref. 25).

Surgeon General's Report, 1988, at 29. *See* AR (Vol. 129 Ref. 1592).

[753] *Regulation of Tobacco Products (Part 3): Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives*, 103d Cong., 2d Sess. 21 (Jun. 21, 1994) (statement of David Kessler) (emphasis added). *See* AR (Vol. 709 Ref. 3).

Brown & Williamson has acknowledged in its comment that the Handbook is a Brown & Williamson document. Brown & Williamson Tobacco Corp., Comment (Jan. 2, 1996), at 37. *See* AR (Vol. 529 Ref. 104).

the smoke. According to William Farone, the former director of applied research at Philip Morris:

> *The use of ammonia chemistry was important to the industry in maintaining adequate nicotine delivery to satisfy smokers. The industry was able to deliver more of the available nicotine in the blend to the smoker by using ammonia compounds. . . .* In the complex world of tobacco smoke chemistry, by increasing the pH of the aerosol in the mainstream smoke, more of the aerosol would be in the vapor phase and less in the liquid (or condensed) phase. *By increasing the ratio of vapor phase to liquid phase, one increases the total nicotine delivery since the condensed phase is less likely to survive the filter and the trip to the lungs.*[754]

Similarly, documents from the American Tobacco Company state:

> There has been an interest in increasing the amount of nicotine that is transferred from the tobacco to the mainstream smoke while leaving the "tar" level unchanged. Since most of the nicotine in tobacco is a non-volatile salt, *it was thought that a greater transfer would take place if the tobacco was made basic causing the nicotine to volatilize when the cigarette is smoked.*[755]

The second effect of increasing the free nicotine is to increase the amount of nicotine absorption that takes place in the mouth. It is well-established that free nicotine is significantly more absorbable than bound nicotine.[756] As early as 1968, researchers at BATCO, Brown & Williamson's parent, reported that there is a direct correlation between smoke pH and nicotine absorption in the mouth, stating that "[n]icotine retention appears

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[754] Farone WA, *The Manipulation and Control of Nicotine and Tar in the Design and Manufacture of Cigarettes: A Scientific Perspective* (Mar. 8, 1996), at 13 (emphasis added). *See* AR (Vol. 638 Ref. 2).

[755] Bodenhamer NL (American Tobacco), Leaf Services Monthly Report for June (Jun. 30, 1980) (emphasis added). *See* AR (Vol. 27 Ref. 385).

[756] *See, e.g.*, Armitage AK, Turner DM, Absorption of nicotine in cigarette and cigar smoke through the oral mucosa, *Nature*, Jun. 27, 1970;226:1231-1232. *See* AR (Vol. 45 Ref. 25).

Surgeon General's Report, 1988, at 29. *See* AR (Vol. 129 Ref. 1592).

to be dependent principally on smoke pH and nicotine content."[757] Similarly, RJR researchers have reported that:

> [B]y raising pH . . . from 6.0 to 6.5 [in a low-tar cigarette] you raise the level of nicotine that is transferred to the taste buds and body fluids in the mouth to the same level as with the higher tar cigarette. *And hence, even though the tar level has been dropped from 25 mg to 10 mg, by raising the pH from 6.0 to 6.5, you increase the nicotine transfer in the mouth. . . .*[758]

This effect of increased nicotine absorption in the mouth appears to be related to what some cigarette manufacturers describe as smoke "impact." For example, Brown & Williamson's Handbook for Leaf Blenders states that by adding ammonia:

> the ratio of extractable nicotine to bound nicotine in the smoke may be altered in favor of extractable nicotine. As we know, extractable nicotine contributes to impact in cigarette smoke and this is how ammonia can act as an impact booster.[759]

RJR describes this effect as "mouth satisfaction," which it distinguishes from "the ultimate satisfaction" which "comes from the nicotine which is extracted . . . in the lungs."[760]

The third effect of increasing free nicotine appears to be to increase the rate of transfer of nicotine to the brain. This effect is discussed in a BATCO research paper

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[757] BATCO, *The Retention of Nicotine and Phenols in the Human Mouth* (1968), at BW-W2-11691. *See* AR (Vol. 445 Ref. 7593).

[758] Senkus M (R.J. Reynolds Tobacco Co.), *Some Effects of Smoking* (1976/1977), at 7 (emphasis added). *See* AR (Vol. 700 Ref. 593).

[759] *Regulation of Tobacco Products (Part 3): Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives*, 103d Cong., 2d Sess. 21 (Jun. 21, 1994) (statement of David Kessler). *See* AR (Vol. 709 Ref. 3).

[760] Senkus M (R.J. Reynolds Tobacco Co.), *Some Effects of Smoking* (1976/1977), at 7, 9. *See* AR (Vol. 700 Ref. 593).

entitled "Further Work on Extractable Nicotine."[761] According to this report, when smoke is inhaled into the lungs, there is virtually complete retention of the nicotine, regardless of whether the nicotine is in its free or bound form. However, the report hypothesizes that the speed of absorption is different when free or extractable nicotine is increased and that "*with a higher 'extractable' nicotine, nicotine reaches the brain more quickly.*"[762] RJR researchers have also recognized that pH adjustments affect the speed of nicotine absorption, recommending that in designing cigarettes for new smokers "[t]he *rate* of absorption of nicotine should be kept low *by holding pH down*, probably below 6."[763]

FDA notes that the use of chemical manipulation to boost free nicotine levels may raise the amount of nicotine delivered to the smoker without a corresponding increase in nicotine yield, as measured by the FTC smoking machine. Thus, the actual nicotine delivery to the smoker from some brands may be higher than the FTC yield because of the addition of ammonia or similar compounds to increase free nicotine.

Based on this evidence, the Agency finds that cigarette manufacturers manipulate and control nicotine deliveries through the use of ammonia compounds. These compounds transform bound nicotine to free nicotine. According to the industry's own documents, this transformation facilitates consumer use of cigarettes for pharmacological

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[761] BATCO, *Further Work on 'Extractable' Nicotine* (1966), at BW-W2-11615 (emphasis added). *See* AR (Vol. 62 Ref. 308).

[762] *Id.* at 7 (emphasis added).

[763] Teague CE (R.J. Reynolds Tobacco Co.), *Research Planning Memorandum on Some Thoughts About New Brands of Cigarettes for the Youth Market* (Feb. 2, 1973), at 4 (emphasis added). *See* AR (Vol. 531 Ref. 125).

purposes by: (1) increasing the amount of nicotine that is transferred from the tobacco to the smoke; (2) increasing the absorption of nicotine in the mouth; and (3) possibly increasing the speed of nicotine transfer to the brain.

d. Nicotine Deliveries Have Increased in Recent Years by Design, Especially in Low-Tar Cigarettes

The use of the methods described above, especially the use of nicotine-rich tobacco blends and selective filtration and ventilation, have increased nicotine deliveries to consumers. In the Jurisdictional Analysis, FDA found that nicotine deliveries as measured by the FTC smoking machine have been increasing since 1982, with the greatest increases occurring in the ultra-low-tar category. *See* 60 FR 41727–41730. These increases have been occurring without parallel increases in tar deliveries, thus indicating an industry-wide trend of designing cigarettes with enhanced nicotine deliveries.

The nicotine/tar ratios in low-tar cigarettes reflect these changes. The Agency's statistical analysis shows that, according to 1994 Federal Trade Commission data, the lowest-tar products had a markedly higher ratio of nicotine to tar than that found in higher-tar products. None of the 153 products with 14 or more milligrams of tar (the high-tar segment of the market) had a nicotine/tar ratio greater than 1 to 12. By contrast, 88 of the 93 products with 6 or fewer milligrams of tar (the ultra-low-tar segment) had a nicotine/tar ratio greater than 1 to 12. *See* 60 FR 41724. The industry did not challenge these figures in their comments.

The increase in nicotine/tar ratios has occurred primarily in the last two decades. In comparison with the 1994 results, only 2 of the 142 marketed cigarettes included in the FTC's report for 1972 had a nicotine/tar ratio greater than 1 to 12. Thus, the evidence

from the reported nicotine and tar deliveries supports the conclusion that as the market for lower tar cigarettes grew over the last 25 years, manufacturers deliberately altered what had been the traditional ratio of nicotine to tar, increasing nicotine levels in relation to tar levels.[764]

This increase in the nicotine/tar ratios is persuasive evidence that the manufacturers design cigarettes to increase their relative nicotine deliveries. Without manufacturer intervention, nicotine levels tend to follow tar levels, because methods that reduce tar deliveries tend to reduce nicotine deliveries as well. As one industry executive testified before Congress, "[n]icotine levels follow the tar level... The correlation ... is essentially perfect correlation between tar and nicotine."[765] The increase in nicotine deliveries relative to tar deliveries indicates that the manufacturers have taken affirmative steps to enhance nicotine deliveries.

The manufacturers dispute this finding. Although they first asserted that nicotine deliveries fall proportionately with tar deliveries, they now assert that the increase in nicotine/tar ratios is due to the unavoidable effects of filtration and ventilation—not any intentional actions of the manufacturers. The record does not support the industry's assertion, however. First, as discussed in section II.C.4.a.ii., above, the cigarette

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[764] Federal Trade Commission, *Report of the "Tar" and Nicotine Content of 142 Varieties of Cigarettes* (Jul. 1972). *See* AR (Vol. 314 Ref. 4856). On a percentage basis, only 1.4% of the 1972 products had a nicotine/tar ratio greater than 1 to 12. In 1994, that figure grew to 26.3% overall, and rose to 95% for the 93 products in the lowest tar category. *Id.*; Federal Trade Commission, *Tar, Nicotine, and Carbon Monoxide of the Smoke of 933 Varieties of Domestic Cigarettes* (1994). *See* AR (Vol. 29 Ref. 485).

[765] *Regulation of Tobacco Products (Part 1): Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives*, 103d Cong., 2d Sess. 143, 378 (Mar. 25, 1994) (statement of Alexander Spears). *See* AR (Vol. 707 Ref. 1).

manufacturers deliberately use tobacco blends with the highest nicotine concentrations in the lowest tar cigarettes.

Second, the record contradicts the industry's contention that they do not control the extent to which filtration and ventilation selectively reduce tar more than nicotine. Indeed, the record indicates that the manufacturers affirmatively use filtration and ventilation to enhance nicotine/tar ratios. *See* section II.C.4.b., above.

Moreover, as the Agency reported in the Jurisdictional Analysis, increases in nicotine deliveries relative to tar deliveries have occurred in all categories of cigarettes. Although the increases in nicotine delivery are largest among the ultra-low-tar cigarettes, relative nicotine deliveries have also been increasing in low-tar and high-tar cigarettes. *See* 60 FR 41727–41731. The manufacturers' theory regarding the unavoidable effects of filtration and ventilation in ultra-low-tar cigarettes cannot explain these other increases in relative nicotine deliveries.

The evidence in the record provides specific examples where manufacturers appear to have designed cigarettes to achieve enhanced nicotine deliveries. As discussed in section II.C.3.b., above, for example, RJR researchers in the mid-1970's recommended "*maintaining the nicotine as high as possible*" in low-tar cigarettes.[766] Researchers specifically recommended that RJR develop a new brand that would deliver 5 mg tar and 0.5 to 0.8 mg nicotine, stating that "*on inhalation into the lungs, 0.5 to 0.8 mg of nicotine*

[766] Senkus M (R.J. Reynolds Tobacco Co.), *Some Effects of Smoking* (1976/1977), at 10 (emphasis added). *See* AR (Vol. 700 Ref. 593).

would provide sufficient nicotine to the blood to produce the stimulation and relaxation effects desired by the smoker."[767]

In the late 1970's and 1980's, RJR began to market ultra-low-tar cigarettes that met these specifications. For instance, RJR first introduced an ultra-light version of its Winston brand in 1981. That year, the Winston Ultra Lights 100's had a tar delivery of 5 mg and a nicotine delivery of 0.5 mg—exactly the deliveries recommended by its researchers as providing the sufficient nicotine to provide the pharmacological effects sought by consumers.[768] As recently as 1994, both the king-size Winston Ultra Lights (hard pack) and the Winston Ultra Lights 100's (hard pack) continued to have these recommended deliveries of 5 mg tar and 0.5 mg. nicotine, as did king-size Camel Ultra Lights and several other RJR ultra-low-tar brands.[769]

Another example of deliberate design to achieve relatively enhanced nicotine deliveries appears to be the Merit Ultra Lights by Philip Morris. Philip Morris researchers conducted extensive research in the 1970's to determine "what combinations of tar and nicotine make for optimal acceptibility in a low delivery cigarette."[770] This research concluded that a higher nicotine/tar ratio (at least 0.09), compared to the natural ratio of

[767] *Id.* at 11-12 (emphasis added).

[768] Federal Trade Commission, *"Tar," Nicotine and Carbon Monoxide of the Smoke of 200 Varieties of Cigarettes* (1981). *See* AR (Vol. 535 Ref. 96, vol. III.D).

[769] Federal Trade Commission, *Tar, Nicotine, and Carbon Monoxide of the Smoke of 933 Varieties of Domestic Cigarettes* (1994). *See* AR (Vol. 29 Ref. 485).

[770] Dunn WL, Johnston M, Ryan F (Philip Morris Inc.), *Plans for 1972* (Sep. 8, 1971), in 141 Cong. Rec. H8128 (daily ed. Aug. 1, 1995). *See* AR (Vol. 711 Ref. 6).